DOCKETS MANAGEMENT BRANCH (HFA-305) FOOD AND DRUG ADMINISTRATION 5630 FISHERS LANE ROOM 1061 ROCKVILLE, MD 20857-0003

RE: DOCKET NO. 98N-1265

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To the FDA:

I send this letter as a consumer of health care services to register my concern and disapproval of the Memorandum of Understanding as published by the FDA on January 21, 1999.

In its present form, the MOU, as well as the Compounding Section 503A of the Modernaztion Act, severely restricts the rights of the physicians and patients to obtain healthcare products from the provider of their choice. It also infringes on the rights of compounding pharmacists to serve the publics medical needs. As a healthcare consumer there should be no restrictions to the delivery of compounded medication prescribed for me, regardless of where I live or travel. The MOU must be amended!!!

The FDA is an agency of the U.S.Government that purports to be the "watchdog" for consumer safety. THIS IS NOT A SAFETY ISSUE!! As a governmental agency, the FDA also has a responsibility to be accountable to the people. Once again, the MOU <u>must</u> be amended!!

I currently use a compounded medication prescribed by my doctor and obtained by mail from another state. I do not want this process to be impeded in any way. Not in my doctor's ability to prescribe nor my ability to obtain this very appropriate and effective medication.

Thank you for your consideration.

Signed: Evelyn H. Shafes
State of Residence: Colorado

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Dockets Management Branch (HFA-305) Food and Drug Administration 5630 Fishers Lane, Room 1061 Rockville, MD 20857-0003

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